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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,169	02/23/2004	Mitchell Karl	43069-0003	8515

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RUDEN, MCCLOSKEY, SMITH, SCHUSTER & RUSSELL, P.A.
P.O. BOX 1900
FORT LAUDERDALE, FL 33301

EXAMINER

SILVERMAN, ERIC E

ART UNIT PAPER NUMBER

1615

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/785,169

Applicant(s)

KARL, MITCHELL

Examiner

Eric E. Silverman, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☒ Claim(s) 4, 7 and 12 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Receipt of the following documents is hereby acknowledged: Oath or Declaration, filed 7/19/2004.

Claim Objections

Claims 4, 7 and 10 are objected to because of the following informalities: Claims 4 and 10 recite "calcium channel clockers." Examiner reads this as an obvious typographical error on the part of Applicant, and for examination purposes will presume that applicant intended "calcium channel blockers" (as is recited in claim 7). Claims 4, 7, and 10 recite "nitroceuticals" and "glycocides." Examiner reads these as a obvious typographical errors on the part of Applicant, and for examination purposes will presume that applicant intended "nutroceuticals" and "glycosides". Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pan et al., US Patent 5,190,970 in view of Endo et al., US Patent 5,569,464 and in further view of Steffen, US Patent 4,693,996.

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Pan teaches the use of two pharmaceutically active agents provided in combination (see abstract). Pan further teaches same when one of the active agents is an angiotensin converting enzyme inhibitor (see abstract) and when the two are mixed in a pharmaceutically acceptable liquid vehicle in appropriate amounts for oral administration (see column 12 lines 17-22).

Pan does not teach the inclusion of osmotic-adjusting agents or buffering agents in the composition, nor does Pan teach the composition where the second active agent is a diuretic, cardiac glycoside, beta blocker, nitrate, antiplatelet, vitamin, nutraceutical, or calcium channel blocker.

Endo teaches an aqueous pharmaceutical composition delivery form comprising the buffer sodium citrate, and vitamins (see column 3 lines 15-26 and column 4, line 41). Endo also teaches the inclusion of pharmaceutically acceptable salts of the hydroxy acids, which includes sodium chloride and potassium chloride (see column 5, lines 16-18).

Steffen teaches aqueous pharmaceutical compositions for the treatment of heart-related ailments that may comprise agents other than the active agents (see, for example, column 3 lines 21-22 and column 4 lines 55 – 68). Stephens further teaches such compositions in an oral unit dosage form, wherein the dosage form is prepackaged (see column 5, lines 1-7). Stephen also teaches a method of making the composition by mixing the active agents and then adding the other agents in appropriate quantities (see column 4, lines 60-63).

Therefore, it would have been prime facie obvious to a person of ordinary skill in the art at the time of the invention to combine the angiotensin converting enzyme inhibitor containing composition of Pan with the vitamin composition of Endo with a reasonable expectation of success. The motivation for doing so is provided by Pan, who teaches that combining angiotensin converting enzyme inhibitor with other medicaments provides increased benefits. Such a composition would obviously include the excipients taught by Endo, in order to realize the full benefits of Endo's delivery form.

It would have been prime facie obvious to a person of ordinary skill in the art at the time of the invention to pre-package this composition according to the teachings of Steffen. Because Stephen describes a composition that is generally similar in nature to that which would result from the combination of Pan and Endo in that it is aqueous, liquid, and has one or more active agents and one or more non-active agents, a person of ordinary skill in the art would have a reasonable expectation of success in carrying out such a manipulation.

It would also have been prime facie obvious to a person of ordinary skill in the art to make the compositions according to the method taught by Stephen. Because Stephen describes a composition that is generally similar in nature to that which would result from the combination of Pan and Endo in that it is aqueous, liquid, and has one or more active agents and one or more non-active agents, a person of ordinary skill in the art would have a reasonable expectation of success in carrying out such a manipulation.

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Furthermore, it would have been prime facie obvious to a person of ordinary skill in the art at the time of the invention to administer the composition for the treatment of a cardiac condition. Because the active agents in the obvious composition are known in the art to be useful for the treatment of cardiac conditions, it would be obvious to administer such a composition in order to treat a cardiac condition. It is obvious to prepare such a composition as an oral dosage form according to Stephen or Pan. An oral dosage form is designed for oral delivery. Thus, it would be further obvious to administer said oral dosage form composition orally, and a person of ordinary skill in the art would have a reasonable expectation of success in doing so.

Conclusion

None of the claims are allowed. None of the claims are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 9:00am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eric E. Silverman
Art Unit 1615



THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600